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July 20, 1978

Yesterday at 3:35 pm we were notified, after a day of cliff-hanging, that JAC had finally signed off the Guidelines, thus moving them into the Federal Register. We promptly had a glass of sherry all around. It was almost a denouement, the reⁿ lease of the Guidelines having been so tragically prolonged. Singer reports much unrest at the Gordon Conference. I meet with environmentalists this morning. They and the scientists are in two different worlds. I urge Singer to encourage the scientists to comment on the Guidelines as soon as they're released. It will be a useful way to work off anxiety and rancor in a hot August. At least we've managed to lock all those concerned into one hearing in September, foiled any prolongation of the comment period, and gained the promise of the Secretary that final Guidelines will emerge no later than 45 days after the of the end of the comment period. Also, there will be no EIS (the Secretary has endorsed our EIA approach). As things look now, there will be no law. There will be a real cause for glowering if I can bring it off procedurally. In long terms, we'll have salvaged everything but a little loss of time, if the biologists will just keep cool. Alas! they will never understand the inevitable delays in what we have tried, and I think succeeded, to do. Or how badly this whole mad episode could have gone, if we had not played each piece so carefully. Now for the end-game!

My first look at the National Security Council today. At least the Policy Review Committee part of it, meeting in a dingy room in the Old Executive Office Building. It was the occasion of Press' report on China. There were 3 star generals present, whose unfamiliar faces reflected the seriousness of this little "peace game". My old traveling companions were back in their hierarchical poses.

It turns out that Joe Califano had delayed work on our Guidelines partly because of a flap over the flu campaign this fall. J. Anthony Morris, a disgruntled employee of the Bureau of Biologics, had stirred up the Post to print a "scandal-manque" on the ACIP meeting in Atlanta. The Senate Committee had junked the supplemental appropriation for the remaining clinical trials. The House is to hear the same Bill today. Thus, Rick Cotton was up all night writing to Flood. John Seal (NIAD Deputy Director) helped Cotton. Seal called me at 7 to review the arguments over how many subjects were to be tested. JAC's position is that all the patients originally planned for testing should be done. Seal's position is that it is unethical to test more than necessary to get a statistically significant answer. Cotton/Levine ask me to call Bob Michels, Republican of Illinois, Silvio Conte, Rep. of Mass., and Tim Lee Carter, Rep. of Kentucky. They all return my calls and all listen courteously to my urging. Conte volunteers to take the HEW remarks to floor and we arrange for Rick to deliver them to the Rayburn Building. The final action saved \$3 million for trials. Nothing was

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awarded for practical use of the vaccine! This is just a typical episode in the continuing drama: "Today-in-Washington".